fitvibemedical

User Manual
Fitvibexcel Pro Medical

Art. nr. 328.882

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1 Safety

CAUTION

Before you start using the Fitvibexcel Pro Medical for the first time, please make sure you have read and understood all information provided in this operating manual.

1.1 Electrical safety

The Fitvibexcel Pro Medical must only be used in spaces and facilities that comply with the relevant legal regulations. The unit must be fitted with a safety plug.

1.2. Explosion protection

The unit is not suitable for use in spaces that contain flammable gasses or vapours.

1.3. Product safety

- Persons suffering or likely to be suffering from one or more of the contra-indications listed under the section “Do not use if...” (in the start menu) may only use the Fitvibexcel Pro Medical following consultation with a medical specialist. Section 3.1 of this User Manual contains a comprehensive list of all contra-indications
- Every person using the Fitvibexcel Pro Medical must check whether any of the listed contra-indications apply of could apply to them (see 3.1)
- The unit is not suitable for use in damp spaces.
- Please keep this User Manual in close proximity to the unit.

1.4. Environmental conditions for transport and storage

While packaged, the Fitvibexcel Pro Medical can be transported and stored (for a maximum of 15 weeks) under the following conditions:

- Temperature range: -20° C to +60° C
- Relative humidity: 10% - 100% including condensation. (please allow device adjust to local temperature before switsching it on.)
- Atmospheric pressure: 500 hPa – 1060 hPa

1.5. Using the Fitvibexcel Pro Medical

The unit must only be operated by authorised personnel. Before you start using the Fitvibexcel Pro Medical for the first time, please make sure you have read and understood all information provided in this User Manual.
Familiarity with the information and instructions contained in this manual is an essential requirement to ensure efficient and optimal use of the system, to avoid dangers to persons and to the equipment and to obtain good results.
The Fitvibexcel Pro Medical vibration platform is designed solely for vibration training and/or treatment. The Fitvibexcel Pro Medical can be operated at ambient temperatures of +10° C to +40° C.

1.6 Conformity

The Fitvibexcel Pro Medical has been developed and is produced, tested and sold according to the international quality management standards EN ISO 9001 and EN ISO 13485. Furthermore, the Fitvibexcel Pro Medical meets the strict requirements of European Medical Device Directive 93/42/EWD, as indicated by the presence of a CE mark (CE0197) on the apparatus. The Fitvibexcel Pro Medical conforms to all of the relevant EMC directive and standard EN 60601-1-2 (IEC 60601-1-2) requirements when used in conjunction with the accessories recommended by the manufacturer. This device

complies with the applicable standard EN 60601-1 (IEC 60601-1). Furthermore, the notified body, TUV Rheinland LGA Products GmbH also carries out checks regularly. This ensures that you are working with equipment that meets all the requirements and provides you and your clients the best possible level of safety.

Please refer to section 6 (ERRORS, WARRANTY, MANTENANCE AND CLEANING) for information on the manufacturers liability.

1.7 Description of used marks and symbols

Applied part type B

CE mark with registration number of the notified body

SN

Serial Number

REF

Article Number

Main Fuse

Year of manufacturing

Manufacturer

Do not dispose this electrical equipment with general house hold waste

General warning sign (ISO 7010-W001)

2 Components and Assembly

2.1 Components and standard accessories

- Vibrating platform with power cable
- Soft mat
- Hand-held remote switch
- Pair of foot straps
- Pair of hand straps
- Assembly tools
- User manual

Art. Nr.	picture	article / description
300240		1 pair of foot straps
300235		1 pair of hand straps
327712		1 soft mat
300234		1 poster with exercises

2.2 Optional accessories

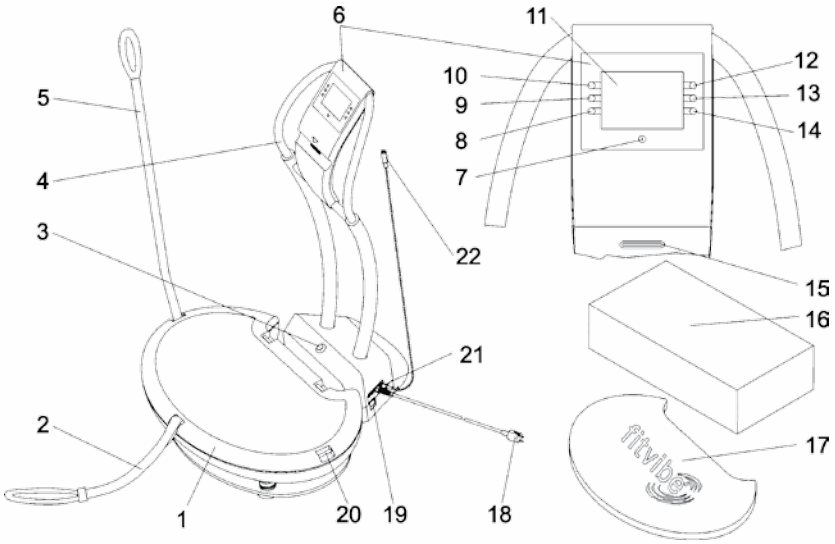
- Fitvibexcel Pro Medical Software

iTS integrated training system software

Art. Nr.	picture	article / description
337612		Fitvibexcel Pro Medical ball
337634		Fitvibexcel Pro Medical push up bars
337656		Fitvibexcel Pro Medical comfort cushion
337645		Fitvibexcel Pro Medical back cushion
337623		Fitvibexcel Pro Medical straps

2.3 Description of the control buttons and accessories

The numerals used in the list below correspond to those used in the diagram.



1. Vibrating platform
2. Foot strap
3. Foot switch (start/stop)
4. Handlebar
5. Hand strap
6. Control panel/display
7. “Start/Stop” button
8. Button
9. Button
10. Button
11. Display
12. Button
13. Button
14. Button
15. Card slot
16. Cushion (Optional)
17. Mat
18. Mains cable
19. Mains switch
20. Attachment point for arm or foot strap
21. Connection socket for hand-held remote switch
22. Hand-held remote switch with Start/Stop button

2.4 Inspection

Please check the Fitvibexcel Pro Medical and accessories upon delivery for any potential damage sustained during transport and whether all of the accessories have been supplied (see section 2.1). Please notify you supplier immediately in the event of transport damage or missing items. Do not use the Fitvibexcel Pro Medical if damaged.
In case of condensation wait for set in operation up to the unit is adapted to the room temperature.

2.5 Mains voltage

The Fitvibexcel Pro Medical is suitable for use with a mains voltage of either 230V, 50-60Hz or 115V, 50-60Hz. Check whether the mains voltage in your area matches the unit's voltage as stated on the label on the rear of the control panel (any voltage higher than that stated can cause irreversible damage to the machine).

2.6 Removing the transportation lock and fitting the handlebar

The transportation lock inside the electronic unit (30) must be removed before starting up the Fitvibexcel Pro Medical. To do so, remove the screws (34) on the base plate (33) of the electronic unit (30) and pull the metal transportation lock (31) out of the unit.

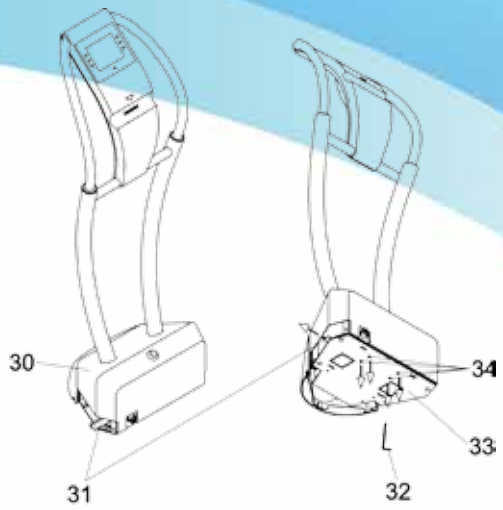


figure 2

The handlebar can only be fitted to the base of the vibration platform once the metal transportation lock has been removed (see figure 3). The electronic unit (30) is fitted onto the base plate of the vibrating unit (1) by using the open-end wrench (48), hexagon head screws (44), spring washers (43) and washers (42). The electronic unit and the vibrating platform are connected to one another using the plug (40) and socket (41). Insert the plug into the socket and secure the connection using the coupling ring of the plug. The two covers (47 and 49) are now fitted over the openings on the electronic unit (30) using the screws (46) and washers (45).

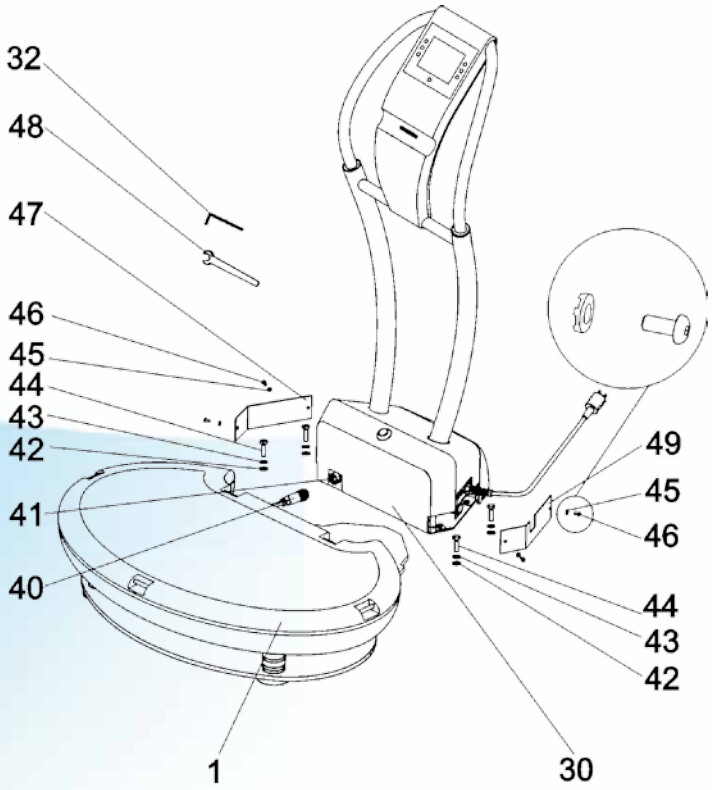


figure 3

2.7 Connecting and switching on the Fitvibexcel Pro Medical

Connect the hand-held remote switch (22) to socket (21). The power input (18) is located on the right side of the electronic unit (30). You can now use the mains switch (19) to turn on the Fitvibexcel Pro Medical. The unit can be used immediately after being switched on.

After switching on the device, a screen mentioning the soft- and hardware revision on the Fitvibexcel Pro Medical appears automatically, followed by a settings menu.

From this menu one can modify the system settings, consult the list of contra-indications or continue to the main screen.

2.8 System settings

The Fitvibexcel Pro Medical vibration platform features a range of system settings that enable you to customize the unit's functions to meet your specific requirements. We recommend using the Fitvibexcel Pro Medical default settings when using the unit for the first time and to customize settings afterwards. The system settings menu can be accessed from the start menu. The arrow buttons in the system settings menu are used to select from the various menu items. The highlighted items show the activated settings.

2.8.1 Language selection

This function is used to select your language. You can set your specific language after selecting the language item from the system settings menu. The following languages are available: English; Dutch; German; Spanish; French; Italian; Norwegian; Polish; Russian; Swedish; Turkish and Portuguese.

2.8.2 Key beep tone

This function is used to turn the beep tone that is sounded when a button is pressed on and off.

2.8.3 Volume

This is where you can adjust the volume of the key beep tone.

2.8.4. Rest Time – end beep

This is where you can turn the acoustic signal marking the end of the Rest Time on and off.

2.8.5. Colours display

Via the field colours display one can switch the background colour of the software as being displayed on screen

2.9. Device settings

2.9.1. Accessing the device settings menu

The device settings menu can be accessed by inserting the configuration card in the card slot of the Fitvibexcel Pro Medical.

Via the button “Next” all “time parameters” are highlighted one after each other. These parameters can be modified with the up and down arrows at the right side.

Furthermore one can modify the time notification towards US or European standards and allowing an automatic summer time setting.

2.9.2. Start Screen*

With this function a user can modify the sequence of the screens depending the way the device is being used in his centre.

***This function is active from software version 3.01 only.**

2.9.3. Fine tuning frequency

In order to avoid resonance in buildings Fitvibexcel Pro Medical has the possibility in an up- or downwards shift of +/- 3Hz.

2.9.4. Balance card

By enabling the balance card, Fitvibexcel Pro Medical will only be accessible when inserting a valid Fitvibexcel Pro Medical card in the card slot (see also the user manual of Fitvibexcel Pro Medical ITS software).

2.9.5. Upload data from Fitvibexcel Pro Medical® ITS software*

Via an USB connection it is possible transferring data from Fitvibexcel Pro Medical® ITS to the device software. Via this menu it is possible to integrate new exercises in the Fitvibexcel Pro Medical database, to change the trainer or to manage the indications menu in the device software.

- Select the data to be modified (exercises, trainer or indications)
- Unsert a, by Fitvibexcel Pro Medical® ITS software programmed USB stick in the right USB slot (looking from the backside)
- Select “Set”
- Wait until a message appears indicating that the USB stick may be removed
- Restart the Fitvibexcel Pro Medical
- Please notice that uploading data from Fitvibexcel Pro Medical® ITS software is only possible with a modified version of Fitvibexcel Pro Medical® Software.

*** This function is active from software version 3.01 only**

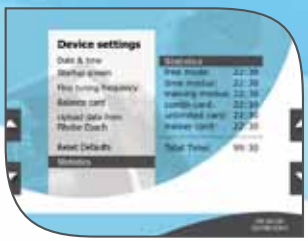
2.9.6. Reset default Settings*

This function is active from Fitvibexcel Pro Medical® software version 2.16 only.

With the optional Fitvibexcel Pro Medical® software it is possible to modify the indications or insert new training programs. With resetting all modifications, data will be reset to the default device settings.

2.9.7. Statistics

In the statistics Fitvibexcel Pro Medical® software menu a Fitvibexcel Pro Medical owner can consult the counter working hours of the Fitvibexcel Pro Medical; the total time Fitvibexcel Pro Medical has vibrated, divided in the different operation modes.



***This function is active from software version 3.01 only**

3 Important information

3.1. "When not to use" – Contra-indications

It is important to make sure that users of the Fitvibexcel Pro Medical vibration platforms do not and are not likely to be suffering from any of the contra-indications listed below before allowing them to commence training. Any person suffering or likely to suffer from any of the contra-indications listed below must not use the vibration platform. Always consult a medical expert, your GP, a consultant or the Fitvibexcel Pro Medical® instructor in case of doubt.
The list of contra-indications is accessible from the first screen.

Absolute contra-indications:	**Relative contra-indications**
	(use Fitvibexcel Pro Medical only after consulting a medical doctor.)
Acute inflammations, infections and/ or fever	Epilepsy
Acute arthropathy and arthrosis	Gallstones, kidney stones, bladder stones
Acute rheumatoid arthritis	Articular rheumatism and arthrosis
Acute headache	Heart failure, insufficiency NYHA III-IV
Postoperative wounds	Cardiac dysrhythmia
Implants / Endoprotheses	Cardiac affections
Metal or synthetic implants (e.g.. pacemaker, artificial cardiac valves, recent stents)	Metal or plastic implants (piercing or gynecologic implants
Acute thromboses or increased thrombotic afflictions (6 months)	Chronic back pain (6 months after acute appearing)
Acute back problems	Severe diabetic mellitus with arterial circulation disorders

Absolute contra-indications:	Relative contra-indications
Pregnancy	Tumors (in a period 5 years plus after appearing, excluding metastases in the musculoskeletal system)
Severe osteoporosis with BMD < 70mg/ml	Spondylolisthesis without gliding
Spasticity	M. Parkinson
Morbus Sudeck Stadium I (CRPS I)	Chondromalasy of the joints of the lower extremities, osteonecrosis and -chondrosis
Tumors with metastases in the musculoskeletal system	Arterial circulation disorders (Stadium Fontaine III°)
Benign Paroxysmal Positional Vertigo (BPPV)	Venous insufficiency with ulcus cruris
	Morbus Sudeck Stadium II (CRPS)
	Lymphatic edema

3.2. Indications

- Postnatal training
- Osteoporoses
- Proprioception
- Lower back pain
- Blood circulation
- Cellulite
- Weight loss

3.3. Important information before using the Fitvibexcel Pro Medical

- Always make sure that you/users do not suffer or are likely to suffer from any of the contra-indications listed under 3.1 before commencing training.
- Always wear sport shoes with flexible rubber soles.
- The first training session must be supervised by an instructor. See section 3.4 “Your first Fitvibexcel Pro Medical workout”.
- Closely follow the instructions on the postures to assume on the unit, on how to carry out the exercises and follow the recommended Rest Times. This will ensure that you get the most out of your training session and will protect you from injuring yourself.

- Drink an isotonic sports drink or some water approx. ½ - 1 hour before your training session.
- The Fitvibexcel Pro Medical vibration platform has been pre-programmed with a training programme specifically designed to gradually get used to exercising on the unit. You may change your exercise programmes following consultation with your Fitvibexcel Pro Medical® instructor.

3.4. Using the softmat

When doing exercises which involve resting on the platform with parts of your body – e.g. your hands, feet or bottom – you need to place the softmat supplied with the Fitvibexcel Pro Medical on top of the vibrating platform.

3.5. Your first Fitvibexcel Pro Medical Work-Out

Before using the Fitvibexcel Pro Medical actively, a first introduction must have taken place to adapt to and get used to the vibrations.

One way to create this adaption is by following next steps:

1. In the Main screen; select “Free parameter”
2. Set the following intensity: 40Hz, Low Amplitude, 30 sec.
3. Put one foot on the platform (wearing sport shoes with no mat on the platform or no sport shoes, with a mat on the platform).
4. Lift your heel from the platform, putting the tension on your calves (always make sure that the muscle you want to train is under pretension).
5. Press the start button
6. Repeat this procedure with the other foot.

With any position standing on the vibration platform, make sure about the following points, before pressing the start button:

- Make sure the tension (leaning) is on the front of you feet, not on your heels
- No locked or overstretched body parts (joints & ligaments)
- Muscles must be pretensioned. (Pretension is necessary to have the muscles absorb the vibrations).
- That the position of the head is levelled.

These steps will make sure that the training or treatment will be comfortable.

3.6. Stop exercising if you're ...

- Feeling dizzy
- Experiencing pain
- Feeling unwell, tense or nauseous.

4 Application

4.1. General

The Fitvibexcel Pro Medical vibration platform generates three-dimensional mechanical vibrations with its main vector being vertical. The Fitvibexcel Pro Medical is extremely easy to use and its operation is based on clear and logical principles. You can use the unit as soon as you have familiarized yourself with the various buttons and their functions. The Fitvibexcel Pro Medical has been pre-programmed with exercise routines both in an “indication” menu as in the menu “training per muscle group”. You can, however, also specify your own exercise parameters using the “Free parameters” menu or the exercise list. This chapter will guide you through all of the options available.

If the card reader in your Fitvibexcel Pro Medical has been enabled (see above) these menus will only be accessible when a valid, by Fitvibexcel Pro Medical ITS software programmed card is inserted in the card lock. Please see point 5 for more information on Fitvibexcel Pro Medical ITS software!

4.2. Exercise on the Fitvibexcel Pro Medical

4.2.1. General operations

The Fitvibexcel Pro Medical vibration platform is operated using the 6 selector buttons and START/STOP button on the control panel. The arrows on the display explain the function of the corresponding button.

4.2.2. Start/Stop button

The Fitvibexcel Pro Medical is equipped with 3 start/stop buttons that can be used to start and stop the vibration mechanism at any time:

- An orange-coloured start/stop button (15), located in the centre on the control panel beneath the display.
- A foot-operated start/stop switch (3), located on the handlebar, at the same level as the vibrating platform.
- A hand-held remote switch (18), which is connected to the control panel by a cable.

You can use any of these buttons to start and stop the vibration mechanism from any posture and position.

4.3. Using the hand and foot straps

The straps are used to transfer the vibration to specific parts of the body, such as the hamstrings, as shown in the illustration. When using straps, the vibrations are transmitted to the relevant parts of the body via the non-elastic strap material. Depending on the particular exercise, the straps can be fastened to any of the fixation point (20) on the vibration platform. The straps have differently coloured reference lines, enabling a correct adjustment and an easier match of their lengths.

4.4. Vibration training parameters

- Vibration frequency: 20 – 60 Hz
- Intensity (Amplitude): high / low
- Active Time: 0 – 180 sec
- Rest Time: 0 – 180 sec
- Exercise type static/dynamic*

*Dynamic exercises are shown dynamically or indicated with an arrow.

4.4.1 Main Screen

The operating system is clear and self explanatory.
In the main screen a user can make a choice out of four options.

Free parameters
Start training immediately and enter your own parameters.

Indications
Select the indication and enter your level, 3D-exercise dynamic pictures will guide you through the training protocol.

Training per muscle group
Select the zone of your body you want to strengthen up. 3D-exercise dynamic pictures will guide you through the protocol.

Exercise list
Choose an exercise from a list and start your training.

All options are made via the up and down buttons followed by “START/STOP”.

4.4.2. Free parameters

A user can:

- Change the amplitude between low and high (also during training or treatment).
- Modify the frequency between 20 and 60 Hz, in steps of 5 Hz
- Change the running time between 0 and 180 seconds.

4.4.3 Indications

A user can:

- Make a choice of indication with the left side buttons
- Make a choice of level with the right side buttons
- Information about the number of exercises; exercise time and total time is shown at the bottom of the display.
- When clicking the button “NEXT” the protocol will be displayed as shown in the below chosen configuration
- The items listed in this screen are manageable via the optional Fitvibexcel Pro Medical® ITS Software.

See also “Upload data from the Fitvibexcel Pro Medical® ITS Software”.

4.4.4. Training per muscle group

When choosing the program “training a muscle group” in the first screen one has to scroll until the wished muscle group is reached. By clicking “NEXT” the following screen will be displayed.

A user can:

- Make a choice of level with the left side buttons
- Make a choice of week with the right side buttons
- Information about the number of exercises; exercise time and total time is shown at the bottom of the display.
- When clicking the button “NEXT” the training protocol will be displayed as shown below in the chosen configuration.

An overview shows how many exercises will have to be performed in the given training menu.

4.4.5. Exercise list

In this menu, a user can scroll until the wished exercise is reached. When the button "?" is clicked the exercise will be loaded. In this menu, all training parameters can be modified. To start the exercise, click on the Start/Stop button. Click on the button to go back to the exercise list.

4.4.6 Exercise

By clicking on the Start/Stop button in the exercise list, a full colour, high resolution 3-D image that is visually self-explanatory, show users clearly how to assume the correct training postures on the Fitvibexcel Pro Medical; additional explanations can also be viewed. Once your training starts, the animated 3-D images display the precise sequence of positions for maximum gain. At the bottom screen a muscle man shows the trained muscle group. Start the exercise by clicking the Start/Stop button again.

Click on the button to go back to the exercise list.

At the bottom frame one can consult the training parameters for the given exercise. When working with the pre-programmed protocols, these data are not changeable.

4.4.7. Active Time and Rest Time

When using the default training protocols, while the vibration is on, the active time is shown on the display and being counted down automatically to 0 sec. Once the active time is finished, the vibration mechanism stops, the next exercise is displayed and the rest time is being counted down.
Once the Rest Time has elapsed, the vibration can be started again using the START/STOP button.

The Rest Time can be skipped by pushing the START/STOP button.
Once the last exercise has been completed, a picture shows “end of exercise”.

4.4.8. Increasing your exercise load

Increasing the load of your training program can be done with vibration training in the following steps:

Creating overload within a basic program (exercises) towards an intermediate program as followed:

1. Increasing the duration of the exercises (Time)
2. Increasing the frequency of the exercises (Hz)
3. Increasing the amplitude of the exercises (Low/High)

Creating overload from an intermediate towards an advanced program as followed:

1. Taking out the balance of the basic exercises.
2. Changing the planes of motion of basic exercises into new movements.

5 Operating

5.1. Operating the Fitvibexcel Pro Medical using Chip Cards

(See device settings, point 2.9.4: “balance card” must be “ON”)

The chip card reader (15) is located right below the control unit (11). Insert the chip card into the reader (15) until it clicks into place. The chip should be located on the top of the Fitvibexcel Pro Medical chip card.

The chip card reader accepts different types of chip cards:

- The chip card, which is used in conjunction with the Fitvibexcel Pro Medical® ITS software and stores all the data relevant to a user.
- The Timecard, which is only used to limit the Active Vibration Time of the Fitvibexcel Pro Medical in accordance with the credit (minutes) available on the card.

The chip card reader recognizes the different types of cards and selects the corresponding operating software automatically.

The “Insert Card” screen can display different types of error messages:

- Chip card inserted incorrectly (insert card correctly – see above).
- Card validity expired (change card validity in the Fitvibexcel Pro Medical® ITS software).
- No training on card.

5.2. Operating the Fitvibexcel Pro Medical using Timecards

A timecard limits the time that the Fitvibexcel Pro Medical vibrates in accordance with the time credits (minutes) available on the chip card. Example: If a Fitvibexcel Pro Medical chip card has a credit of 30 minutes of vibration training time, you can exercise on the unit for a total of 30 minutes of vibration training time, i.e. any Rest Times are not charged to the card. The exercise time credits on the card can also be used on different days. When the time credits (minutes) on

the Fitvibexcel Pro Medical chip card have been used up, the card's credits can be topped up by using the card top-up unit.
The Fitvibexcel Pro Medical can still be operated even if the time credits available on the chip card are insufficient for a particular series of exercises. Should this be the case, the unit will continue to operate and vibrate until the available time credits have been used up. The Fitvibexcel Pro Medical chip card can be charged with a maximum of 999 minutes of exercise time credits. Please refer to the card top-up unit's user instructions for more information on how to operate the device.
Once the Timecard has been read by the Fitvibexcel Pro Medical unit, it will open the "Main screen" page. From this point onwards, Fitvibexcel Pro Medical's that have their card readers enabled are operated in the same way as Fitvibexcel Pro Medical whose card readers are disabled (see point 4).

5.3. Operating the Fitvibexcel Pro Medical using chip cards charged via the Fitvibexcel Pro Medical ITS Software

The chip cards carry the data for self-designed Fitvibexcel Pro Medical exercise or treatment programmes. Use of the Fitvibexcel Pro Medical® ITS software cards requires the easy Fitvibexcel Pro Medical® ITS software to be installed on your computer and using the associated writer.

Please refer to the associated Fitvibexcel Pro Medical® ITS Software user instructions for information on how to use the software.

Once the Fitvibexcel Pro Medical® unit has read the Fitvibexcel Pro Medical® ITS chip card, you will be shown the "Welcome" page.

On the “Welcome” page, you can choose whether to use the pre-programmed training protocols on the chip card or to deduct time only in the free menu. If your chip card has been charged with extra exercising time credits, you will be taken straight to the main menu after having choosing “Timecard”. Please refer to point 5.1 and 4 of this user manual for information on how to proceed from this point.

In addition to the other information, the screen will also display the current exercise programme code, the total number of exercise programmes stored on the Fitvibexcel Pro Medical® ITS chip card and the name of the exercise programme.

If you select the pre-programmed training protocols on the “Welcome” page, you will be taken straight to the diagram showing the first exercise. You can now start the vibration plate by pressing the START/STOP button.

You can skip exercises by using the “NEXT” (14) button and you can go back to those exercises using the “BACK” (8) button.

It is not possible to return to a skipped exercise once you have started on the next one.
Example: the exercise programme you have selected contains 6 individual exercises. You completed the first of those 6 exercises, skipped the second and third, and are now starting on the fourth – this means that you cannot now return to the second and third exercise.

If you accidentally skipped the last of a series of exercises, you will be shown the “End of Exercise Programme” page.

Once you have removed the chip card from the card reader, you will always be taken back to the “Welcome” page. When re-inserting the chip card, you can continue your training programme by either starting on the next exercise programme or the next exercise of an exercise programme that you haven’t yet finished.

Following completion of all exercises, it is not possible to continue using the chip card without re-programming it, unless the card was issued without any “time limits”, in which case it can be used for an infinite number of times.

6 Errors, guarantee, maintenance and cleaning, decommissioning

6.1 Errors

- THE UNIT CANNOT BE SWITCHED ON
  Check whether the mains power is on, the mains switch is turned on and whether the power cable and the fuses are OK. You can replace any faulty fuses yourself. Please only use fuses of the type stated on the unit's rating plate. Replacement fuses can be ordered from your supplier.
- THE DISPLAY SHOWS MESSAGES IN A FOREIGN LANGUAGE.
  Go to the system settings menu and select the required language. Please get in touch with your supplier should this error continue to occur.
- NONE OF THE CONTROL ELEMENTS WORK
  Turn off the unit and turn it on again. Please get in touch with your supplier should this error continue to occur.

6.2. Guarantee

6.2.1. Terms of guarantee

Guarantee period of the Fitvibexcel Pro Medical is 24 months and begins at the date of purchase (the proof is the date on the invoice). This guarantee includes all defects of materials and production quality.

The guarantee applies only for using the unit according to the intended purpose and observing the instructions for use.

The guarantee does not apply for cases of poor maintenance, wrong implementation of an error and when maintenance and/or repair work was performed by persons, who were not authorized by the GymnaUniphy Company, and, of course, for accidents and damages caused by the above-mentioned cases.

6.2.2. Limitation of the manufacturer's liability

The manufacturer is not liable for possible follow-up damages/ injuries at therapists, instructors, users or the equipment used, which are caused by wrong diagnosis, improper use of device and/or accessories, misinterpretation or non-compliance with this user manual, poor maintenance of the unit or when the unit was maintained by persons that were not authorized by the manufacturer for that purpose.

6.3 Service

- All repairs, modifications and upgrades must be performed/ implemented by authorised personnel only;
- The electrical wiring of the space in which the unit is set up must comply with the relevant legal regulations;
- The unit must only be used for its intended purpose;
- The unit must be serviced regularly and in accordance with the relevant instructions;
- The legal regulations regarding the use of the unit must be observed at all times.

Uniphy Elektromedizin GmbH & Co. KG and its representatives shall not be held responsible for damage, injuries, faults or malfunctions caused as a result of improper use or failure to observe maintenance instructions. Servicing and warranties are provided by your supplier. The warranty becomes void if the unit is not used in accordance with the above instructions.

Should you have any further questions or require additional information, please feel frre to contact your dealer.

6.4. Maintenance

It is recommended that a specialist services the unit annually. When doing so, the following areas need particular attention:

- Check all screws and mechanical clamp joints
- Visually check all cables and their connectors
- Check the functioning of the hand-held remote and foot switch
- Check the rubber springs for signs of mechanical damage
- Check the rubber O-ring inside the motors.

6.5. Cleaning

The vibrating platform, control unit and all accessories can be cleaned using a damp cloth. Only use mild, non-abrasive cleaning agents! The handlebar can be cleaned using a standard surface disinfectant.

6.6. Decommissioning and disposal

When you wish to dispose your Fitvibexcel Pro Medical unit, you can follow two ways:

- You can bring the unit and its accessories to a disposal company that specialises in electronic products or that has means of forwarding the unit to such a company. If you live in a country where suppliers are legally obliged to dispose of their products, you can return the unit to your local supplier.
- Due to the type of plastic and electronic components they contain, most countries prohibit disposal of these kinds of units as ordinary household waste. For the event that you chose to dispose of the unit yourself or are accepting responsibility for its disposal, we would like to provide you with the following environmental information:

The components of the Fitvibexcel Pro Medical vibration platform can be divided into three categories:

- The vibration platform, control panel, cables, straps and soft cover (mat) are classed as electronic or non-hazardous chemical waste. Amongst other things, these components contain lead, tin, copper, iron and various other metals and types of plastic. In most countries, this type of waste is classed as non-hazardous chemical waste and must be disposed of in accordance with the relevant local regulations.
- Packaging materials and manuals are recyclable and can be disposed of at recycling centres of as household waste, depending on local waste disposal regulations.
- The information supplied above also applies to the unit's accessories.

The device complies with the essential requirements of the Waste Electrical and Electronic Equipment (WEEE) directive 2003/108/EC of the European parliament and of the oncil as most recently changed.

7 Technical Data

Vibration plate:

- Vertical vibration amplitude 1,5 & 3 mm
- Ergonomic handle
- Start / stop on plate
- Extra large exercise surface
- Frequency 20 – 60Hz adjustable per 5Hz
- 5 Fixation points for straps

Handle

- Integrated card reader
- Electronics insulated from vibration
- Start/stop on display
- Start/stop by remote control

Software

- Quick start
- Dynamic 3-D pictures
- Colour screen
- Integrated training software
- Indication & contra-indication list
- Training & Time card feature

Standard accessories

- Foot straps (1 pair)
- Hand straps (1 pair)
- Remote control
- Soft mat
- Exercise poster

Technical specifications:

- Weight: 120 kg
- Dimensions: 1050 x 990 x 1440 mm
- Maximal static load: 250 kg (dynamic proportions 20%)
- Noise level: max 71 dBa
- Standard colour: grey, white, black

- Supply voltage: 230V +/- 10%, 50/60Hz
  115V +/- 10%, 50/60Hz
- External fuses: 10AT (local electric installation)
- Miniature fuses: T2AL for 230V
  T4AH for 115V
- Power consumption: max 420 VA
- Protective system: I
- Type of protection: Type B
- Degree of protection: IP20
- Transport and storage conditions:
  In the manufacturers package at following limits:
  -20 °C to +60 °C
  5% to 100% humidity including condensation
  500 hPa to 1060 hPa atmospheric pressure
- Operating condition:
  +10 °C to +40 °C ambient temperature
  5% - 90% air humidity, non condensing

This medical device complies with the applicable standards EN 60601-1-1 a (IEC 60601-1) and EN 60601-1-2 (IEC 60601-1-2) and with Medical Device Directive (MDD) 93/42/EEC. Classification in accordance with MDD is IIa

8 References to the electro-magnetic comptability requirements (EMC)

The Fitvibexcel Pro Medical conforms to all of the relevant EMC directive and standard EN 60601-1-2 (IEC 60601-1-2) requirements when used in conjunction with the accessories recommended by the manufacturer.
Please read and observe the information relating to the EMC in the user instructions and in this and any other accompanying documents before installing and using the Fitvibexcel Pro Medical.
You have acquired a device that was developed and produced in accordance with the latest technological advances in conformity with the above EMC directive. Fitvibexcel Pro Medical is protected against interference and does not interfere with other electrical devices in accordance with the standards it complies with.

EN 60601-1	
- Type of protection against electric shocks:	class 1
- Degree of protection against electric shocks:	B

EMC guidance and manufacturer's declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The model Fitvibexcel Pro Medical is intended to use in the electromagnetic environment specified below. The customer or the user of the Fitvibexcel Pro Medical should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Fitvibexcel Pro Medical uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. According to IEC 60601- 2-36 this doesn't comply during the generation and release of shockwaves.
RF emissions CISPR 11	Class B	The Fitvibexcel Pro Medical is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The model Fitvibexcel Pro Medical is intended to use in the electromagnetic environment specified below. The customer or the user of the Fitvibexcel Pro Medical should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / Bursts IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	± 2kV for power supply lines ± 1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U (> 95 % dip in) for 0.5 cycle 40 % U (60 % T in U) for 5 cycles 70 % U (30 % dip in U) for 25 cycles < 5 % U (> 95 % dip in U) for 5 s	< 5% U (> 95 % dip in U) for 0.5 cycle 40 % U (60 % dip in U) for 5 cycles 70 % U (30 % dip in U) for 25 cycles < 5 % U (> 95 % dip in U) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Fitvibexcel Pro Medical requires continued operation during power mains interruptions, it is recommended that the Fitvibexcel Pro Medical be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should be that of a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The model Fitvibexcel Pro Medical is intended to use in the electromagnetic environment specified below. The customer or the user of the Fitvibexcel Pro Medical should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Cmpliance level	Electromagnetic environment - guidance
			Portable and mobile RF equipment should be used no closer to any part of the Fitvibexcel Pro Medical, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	d = 1,2√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	d = 1,2√P 80 MHz to 800 MHz d = 2,3√P 800 MHz to 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation distance in metres [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Fitvibexcel Pro Medical

The Fitvibexcel Pro Medical is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Fitvibexcel Pro Medical can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fitvibexcel Pro Medical as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter [m]		
Rated maximum output power of transmitter [W]	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres [m] can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

NOTE 1
At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

NOTE 2
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Your local supplier is:

Fitvibexcel Pro Medical
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Fitvibexcel Pro Medical® is a division of GymnaUniphy NV